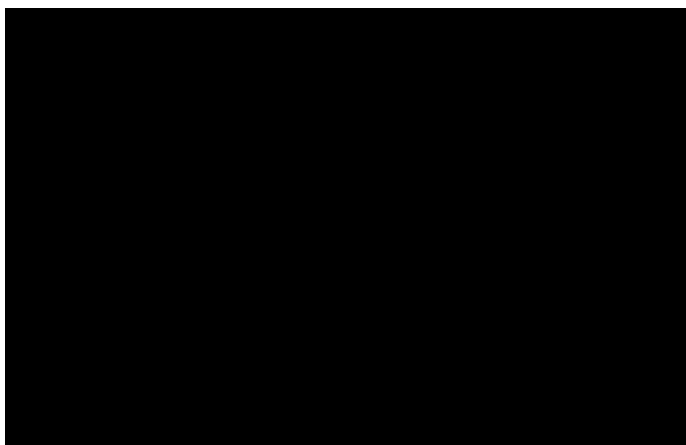




Medicines & Healthcare products
Regulatory Agency

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gov.uk/mhra



09 August 2023

Dear 

FOI 23/394

Thank you for your communication, dated 23 May 2023, in which you requested Module 2.4, Module 2.5 and Module 5.3.1 submitted for Glycopyrronium Bromide 1 mg and 2 mg Tablets (Kinedexe UK Limited).

Marketing Authorisations for Glycopyrronium Bromide 1 mg and 2 mg Tablets (PL 15764/0156-0157) were granted to Strandhaven Limited t/a Somex Pharma on 11 and 22 March 2021, respectively, following change of ownership procedures of Glycopyrronium Bromide 1 mg and 2 mg Tablets (PL 44710/0017-0018). Glycopyrronium Bromide 1 mg and 2 mg Tablets (PL 44710/0017-0018) were granted to Kinedexe UK Limited on 20 April 2016.

In response to your request, please find attached Module 2.4 (non-clinical overview), Module 2.5 (clinical overview) and study reports 13-021, 068-20 and 934-19 from Module 5.3.1 submitted to support the variation to change the therapeutic indication for Glycopyrronium Bromide 1 mg and 2 mg Tablets (PL 44710/0017-0018) from 'For use in adults as an add-on therapy in the treatment of peptic ulcer', to the new indication of 'Symptomatic treatment of severe sialorrhoea (chronic pathological drooling) due to chronic neurological disorders of childhood onset in patients 3 years and older.' Please note that the documentation has been

redacted under Section 40 (Personal information), Section 41 (Information given in confidence) and Section 43 (Commercial interests) of the Freedom of Information Act.

Disclosure of information subject to Section 40 (Personal information) would be an infringement of personal data. Section 40 (Personal information) is an absolute exemption, and no consideration of the public interest is required.

Section 41 (Information given in confidence) is an absolute exemption, and no consideration of the public interest is necessary, except to state that the release of this information withheld under this section of the FOI Act would be considered an actionable breach by the MHRA.

We have redacted some parts of the attached documentation under Section 43 (Commercial interests) of the FOI Act because the release of all, or part of, the information would, or would be likely to, cause harm to the third party's commercial interests. The exemption is to safeguard the commercially sensitive information/commercial enterprise. In this case, release of information would enable the competitors to overcome several regulatory hurdles in the research and development of their own products. This exemption is conditional on the public interest in releasing it not outweighing the company's/commercial enterprise's right to confidentiality and the probable damage that the company/commercial enterprise could suffer as a result of the information being released. We have considered the balance of the public interest when applying this exemption. In this case, we have not identified any issues which would benefit the public, as a whole, by being brought to their attention.

Please also note that the documentation is historical and variation applications may have been submitted subsequently to update some of the information included.

We now consider this FOI request closed.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within 2 months of the date you receive this response and addressed to: info@mhra.gov.uk, quoting reference FOI 23/394.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request, unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, and Cheshire, SK9 5AF.

Yours sincerely,

The FOI Team,
Healthcare, Quality and Access.

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